REMARKS

A. Status of the Claims

Of the fifteen claims 1-15 originally filed in this application, claims 1-10 and 14-15 are withdrawn from consideration and claims 11-13 are under examination. Claims 11-13 currently stand rejected as follows:

(a) Claims 11-13 are rejected under 35 U.S.C. § 102(b), for allegedly being anticipated by Wessels et al. (Infection and Immunity, vol. 66, no. 5, pp. 2186-2192, May 1998, hereafter "Wessels I").

(b) Claims 11-13 are rejected under 35 U.S.C. § 102(b), for allegedly being anticipated by Wessels et al. (Journal of Clinical Investigation, vol. 86, pp. 1428-1433, November 1990, hereafter "Wessels II").

(c) Claims 11-13 are rejected under 35 U.S.C. § 102(b), for allegedly being anticipated by Michon et al. (In Streptococci and Host. (Ed). Horaud et al., Plenum Press, New York, pp. 847-850, 1997, hereafter "Michon I").

(d) Claims 11-13 are rejected under 35 U.S.C. § 102(b), for allegedly being anticipated by Jennings et al. (U.S. Patent No. 5,993,825, hereafter "Jennings").

(e) Claims 11-13 are rejected under 35 U.S.C. § 102(e), for allegedly being anticipated by Michon et al. (WO 2004/0111027, hereafter "Michon II").

(f) Claims 11-13 are rejected under 35 U.S.C. § 102(e), for allegedly being anticipated by Michon et al. (U.S. Patent No. 6,602,508, hereafter "Michon III").

B. Explanation of the Amendments

In this paper, Applicants have amended the specification to provide the full name and description of abbreviations when they first appear in the specification. Applicants have also amended the specification to capitalize trademarks as requested by the Examiner. Additionally, Applicants have made amendments to the specification to correct minor typographical errors. No new matter has been added by these amendments.

C. Rejections under 35 U.S.C. §102(b)

Applicants respectfully traverse the rejection of claims 11-13 under 35 U.S.C. § 102(b), for allegedly being anticipated by Wessels I, Wessels II, Michon I and Jennings. Briefly, the prior art references do not disclose all of the features of the claimed invention. Accordingly, the rejection should be withdrawn.

Independent claim 11 reads as follows:

> 11. A conjugated vaccine comprising an antigen that has been conjugated to Fragment C, wherein said antigen is a capsular polysaccharide.

The Examiner contends that Wessels I, Wessels II, Michon I and Jennings anticipate claims 11-13, because these references purportedly disclose all of the claimed features of the invention, including "Fragment C" of tetanus toxin. Office Action, ¶¶ 8-11. In making this rejection, the Examiner acknowledges that none of these references explicitly disclose "Fragment C," but contends that this claimed feature is inherently disclosed by the description in these references of a conjugate vaccine in which a capsular polysaccharide is conjugated to tetanus toxin. According to the Examiner, the disclosure of the tetanus toxin discloses Fragment C, "because this fragment is inherently included in full length tetanus toxin." Id.

However, the Examiner's reading of the claims is inconsistent with the teachings of Applicants' specification, and therefore improper in view of well-established case law from the Court of Appeals of Federal Circuit (CAFC). In particular, the CAFC has held that the claims are to be determined "in light of the specification." For example, in Phillips v. AWH Corp., 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005), the CAFC stated that

> [t]he Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art."

Phillips at 1316 (emphasis added).

Here, Applicants' originally filed specification clearly discloses that Fragment C does not refer to the entire tetanus toxin molecule:

> Thus, in the context of the present invention, Fragment C refers to separation of the region from at least a portion of the remainder of the whole tetanus toxoid molecule, which can be done by digestion of the toxoid with papain or other proteases or through recombinant expression of the fragment.

Original specification, ¶[22]. Thus, the Examiner's reading of the term "Fragment C" in claim 11 to encompass the full length tetanus toxin molecule plainly contradicts the teachings of the specification as they would be interpreted by one of ordinary skill in the art. In other words, one of ordinary skill in the art would understand, based on the specification, that the phrase "an antigen that has been conjugated to Fragment C" in claim 11 does not refer to conjugating the antigen to a full length tetanus toxin. The Examiner's interpretation of the term "Fragment C" contradicts the specification and is therefore inconsistent with well-established CAFC case law.

Accordingly, Applicants respectfully submit that claim 11 is not anticipated by Wessels I, Wessels II, Michon I or Jennings when the language of claim 11 is read faithfully in

view of the specification. As these references only refer to the full length tetanus toxin molecule, none of these references disclose "Fragment C" as recited in Applicants claims. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 11-13 under 35 U.S.C. §102(b).

D. Rejections under 35 U.S.C. §102 (e)

Applicants respectfully traverse the rejection of claims 11-13 under 35 U.S.C. §102(e) for allegedly being anticipated by Michon II and Michon III. As discussed in detail below, neither reference discloses "Fragment C" as recited in Applicants' claims. Accordingly, the rejection should be withdrawn.

According to the Examiner, Michon II discloses Fragment C of tetanus toxin in claims 5, 36, 43 and on page 4 and 6. Office Action, ¶12. Applicants respectfully disagree. These cited portions of Michon II do not disclose Fragment C, but instead only refer to Cα and Cβ carriers, which the Examiner erroneously reads as a disclosure of Fragment C. However, it is well known in the art that Cα and Cβ carriers are derived from Group B *Streptococcus*, whereas tetanus toxin is derived from *Clostridium tetani*, a completely different organism. In fact, Michon II itself clearly states that Cα and Cβ are derived from Group B *Streptococcus*:

> In further examples, such as a multivalent conjugate molecules that comprise Group B *Streptococcus* capsular polysaccharide, a **Cα or Cβ carrier is often used. The C protein(s) are a group of a cell surface associated protein antigens of Group B *Streptococcus*** *(see, e.g.,* Wilkinson *et al., J. Bacteriol.* 97:629-634 (1969), Wilkinson, H. W, *et al., Infec. and Immun.* 4:596-604 (1971)). Two antigenic ally distinct populations of C proteins have been described, those that are sensitive to 30 degradation by pepsin but not by trypsin, Cα. and. those that are sensitive to degradation by both pepsin and trypsin, Cβ Method of producing Cα and Cβ and analogs of the proteins are described, *e.g.,* in U.S. Patent 5,908,629.

Thus, the skilled artisan would understand that Cα and Cβ carriers are not derived from tetanus toxin and are not Fragment C. Neither the passages of Michon II relied upon by the Examiner nor any other passage of Michon II discloses Fragment C. Accordingly, the rejection of Applicants' claims over Michon II is improper and should be withdrawn.

With respect to Michon III, the Office Action states that Michon III "teach[es] fragments of tetanus toxin with molecular weight of 15, 33, and 51 kilo Dalton" and "teach[es] Fragment C, i.e., the 51 kDa fragment." [Office Action, ¶13 (citing the abstract, claims, and Columns 3 and 9 of Michon III)]. Applicants respectfully disagree. The Examiner's rejection appears to be based upon a misreading of Michon III, because the cited passages of Michon III actually refer to the molecular weight of various polysaccharide fragments, rather than to the molecular weight of protein fragments, such as Fragment C. For instance, Column 3 of Michon III clearly indicates that the 15, 33, or 51 kilodalton fragments are that of type II polysaccharide, rather than tetanus toxin:

> FIG. 1. Direct binding of rabbit anti-type II specific polysaccharide antibody to **type-II-fragment polysaccharide**-tetanus toxoid conjugates (**with fragments of average molecular weights 15, 33 and 51 kilodaltons**) compared with the binding to the **type II native polysaccharide (200 kilodaltons)**-tetanus toxoid conjugate taken as 100% binding reference.

Nowhere does Michon III disclose a 51 kDa fragment of a tetanus toxin molecule that corresponds to Fragment C. Thus, Applicants maintain that Michon III does not anticipate claims 11-13 of Michon III and request reconsideration and withdrawal of this ground of rejection.

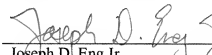
AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 50-3732, Order No. 13564-105027.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-3732, Order No.13564-105027.

Respectfully submitted,
KING & SPALDING, L.L.P.

Dated: September 21, 2009

By: 

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